GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA

UNSTARRED QUESTION NO:5495
ANSWERED ON:29.04.2003
LIFE SAVING MEDICINES
BASUDEB ACHARIA

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) the measures taken by the Government to maintain price caps on life saving medicines while implementing new pharmaceutical policy;

(b) the details of new criteria of market share and turnover evolved by the Government in the new pharmaceutical policy;

(c) whether these criteria will lead many essential drugs being taken out of price control list;

(d) if so, the facts thereof; and

(e) the corrective measures taken by the Government in this regard?

Answer

THE MINISTER OF CHEMICALS & FERTILIZERS (SHRI SUKHDEV SINGH DHINDSA)

(a) to (e) : Government announced the `Pharmaceutical Policy-2002` in Febraury,2002copies of which are available in the Parliament liabrary. The main objectives of the Policy are, interalia, ensuring abundant availability at reasonable prices within the country of good quality essential pharmaceuticals of mass consumption and strengthening the indigenous capability for cost effective quality production. The Policy provides, inter-alia, as follows :-

(i) The 279 items appearing in the alphabetical list of Essential Drugs in the NationalEssential Drug List (1996) of the Ministry of Health & Family Welfare and the 173 items, which are considered important by that Ministry from the point of view of their use in various Health Programmes, in emergency care etc., with the exclusion,. therefrom of sera & vaccines, blood products, combinations etc., should form the total basket out of which selection of bulk drugs be made for price regulation.

(ii) The Org-MARG data of March, 2001 would form the basis for determining the span of price control.

(iii) The Moving Annual Total (MAT) value for any formulator in respect of any bulk drug will be arrived at by adding the MAT values of all his single-ingredient formulations of that bulk drug, its salts, esters, stereo-isomers and derivatives, covering all the strengths, dosage forms and pack sizes listed against that formulator in all groups /categories of the ORG-MARG (March, 2001).

(iv) The MAT value for all the formulators, as defined in sub-para
(iii) above, in respect of a particular bulk drug will be added to arrive at the total MAT value in the retail trade.

(v) The MAT value for an individual formulator, in respect of any bulk drug, as arrived at in sub-para (iii) above, will be the basis for calculating the percentage share of that formulator in the total MAT value arrived at as in sub-para
(iv) above, in respect of that bulk drug.

(vi) Bulk Drugs will be kept under price regulation if :-

(a) The total MAT value, arrived at as in sub-para
(iv) above, in respect of any particular bulk drug is more than Rs.2500 lakhs (Rs.25 Crore) and the percentage share, as defined in sub-para
(v) above, of any of the formulators is 50% or more.

(b) The total MAT value, arrived at as in sub-para
(iv) above, in respect of any particular bulk drug is less than Rs.2500 lakhs (Rs.25 Crore) but more than Rs.1000lakhs (Rs.10 Crore) and the percentage share, as defined in sub-para
(v) above, of any of the formulators is 90% or more.

(vii) All formulations containing a bulk drug as identified above, either individually or in combination with other bulk drugs, including

those not identified for price control as bulk drug, will be under price control.`

A Public Interest Litigation in Karnataka High Court resulted in an order dated12.11.2002 which stopped the Government from implementing the price control regime of the Pharmaceutical Policy-2002. Government have fileda Special Leave Petition in the Supreme Court against the order of the Karnataka High Court.